

K111323

NOV 16 2011

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## 510(k) Summary

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<b>Date Prepared</b>	August 30, 2011
<b>Submitter</b>	SYNTHERS (USA) 1301 Goshen Parkway West Chester, PA 19380 United States of America
<b>Contact</b>	Contact: Alan T. Haley haley.alan@synthes.com (484) 356-9763
<b>Trade Name</b>	Synthes SynPOR HD Porous Polyethylene Three Dimensional Implants Synthes SynPOR HD Facial Shape System Synthes SynPOR HD Ocular Spheres
<b>Common Name</b>	Porous High Density Polyethylene (HDPE) Implant
<b>Classification Name</b>	Material, polytetrafluoroethylene vitreous carbon, for maxillofacial reconstruction, Class II, 21 CFR 878.3500
<b>Product Code</b>	KKY
<b>Predicate Devices</b>	AOC Porous Polyethylene Surgical Implants (K080507)
<b>Device Description</b>	SynPOR HD Porous Polyethylene Three Dimensional Implants are devices intended for ocular reconstruction and socket preservation, enhancement of the midface and mandibular skeleton, and correction of deficiencies of the midface and mandible. The porous structure of the HDPE material allows for fibrovascular ingrowth.  The implants include facial shapes (chin and malar implants for aesthetic and reconstructive surgery to augment the contours of the craniofacial skeleton) and ocular spheres (for restoring the volume of an eviscerated or enucleated eye globe).  SynPOR HD Porous Polyethylene Implants are delivered sterile for single patient use and should not be resterilized.
<b>Intended Use</b>	Synthes SynPOR HD Porous Polyethylene Three Dimensional Implants are intended for the augmentation or reconstruction of the craniomaxillofacial skeleton.
 Specific indications (SynPOR HD Ocular Spheres):	
<ul style="list-style-type: none"> <li>• Ocular reconstruction</li> <li>• Socket preservation</li> </ul>	
 Specific indications (SynPOR HD Facial Shapes):	
<ul style="list-style-type: none"> <li>• Enhancement of the malar and chin</li> <li>• Correction of deficiencies of the malar and chin</li> </ul>	

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<b>Technological Characteristics</b>	Synthes SynPOR HD Porous Polyethylene Three Dimensional Implants are modifications to the predicate and are therefore similar in terms of indications, materials, principles of operation, dimensions, and design. It was determined that none of the modifications impact safety and effectiveness.
<b>Substantial Equivalence to Predicate Devices</b>	The modified devices are similar to the predicate devices identified above in terms of indications, materials, principles of operation, dimensions, and device design. The information presented in this submission supports substantial equivalence of the Synthes SynPOR HD Porous Polyethylene Three Dimensional Implants to the predicate device.

**(end of summary)**



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Synthes, Inc.  
% Mr. Alan T. Haley  
Regulatory Affairs Specialist  
1301 Goshen Parkway  
West Chester, Pennsylvania 19380

NOV 16 2011

Re: K111323

Trade/Device Name: Synthes SynPOR HD Porous Polyethylene Three Dimensional Implants

Regulation Number: 21 CFR 878.3500

Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material

Regulatory Class: II

Product Code: KKY

Dated: November 11, 2011

Received: November 14, 2011

Dear Mr. Haley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



## Indications for Use Statement

510(k) Number (if known): K111323

Device Name: Synthes SynPOR HD Porous Polyethylene Three Dimensional Implants

Indications for Use: Synthes SynPOR HD Porous Polyethylene Three Dimensional Implants are intended for the augmentation or reconstruction of the craniomaxillofacial skeleton.

Specific indications (SynPOR HD Ocular Spheres):

- Ocular reconstruction
- Socket preservation

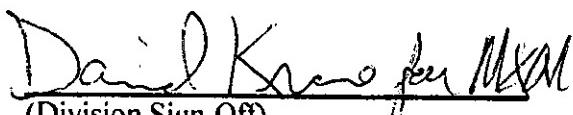
Specific indications (SynPOR HD Facial Shapes):

- Enhancement of the malar and chin
- Correction of deficiencies of the malar and chin

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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